

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60147504 0001

Report No.: 12031273 015

Manufacturer: Shimadzu Corporation

Medical Systems Division

1, Nishinokyo-Kuwabaracho

Nakagyo-ku, Kyoto 604-8511 Japan

Products: Diagnostic X-Ray Devices, Angiographic X-Ray Diagnostic

Systems, X-Ray Tube Assemblies

Near Infrared Fluorescence Imaging System and Workstation software for Diagnostic X-Ray Systems

Replaces Approval, Registration No.: HD 60130116 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date:

2020-06-01

Date:

2020-06-01

Notified Body

Takashi Matsuda

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜVRheinland



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

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Attachment to Certificate

Registration No.:

HD 60147504 0001

Report No.:

12031273 015

604-8511 Japan

Manufacturer:

Shimadzu Corporation Medical Systems Division 1, Nishinokyo-Kuwabaracho Nakagyo-ku, Kyoto

Site included:

Shimadzu Corporation Sanjo Works (Shimadzu Corporation Sanjo Factory)

1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto, 604-8511, Japan

Date: 2020-06-01



Notified Body

Takashi Matsuda